FDA 510(k) Premarket Notification

K894681 REVISED LABELING FOR ARTERIAL EMBOLECTOMY CATHETER

CLEARED

Oct 12, 1989
79 days to decision

K894681 · Product code: **DXE** · Cardiovascular
Source: https://www.510kdatabase.net/k894681/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Jul 25, 1989
Decision date	Oct 12, 1989
Days to decision	79 days
Third-party review	No

APPLICANT

Company	**Shiley, Inc.**
Location	Mchenry, IL, US
Contact	LOUIS J MAZZARESE
510(k) history	174 submissions · 174 cleared · 1976-1993